DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

I-012781-X-0001-CE

USDI Fish & Wildlife Service
Aquatic Animal Drug Approval Partnership Program
Attention: David Erdahl, Ph.D.
Branch Chief
4050 Bridger Canyon Road
Bozeman, MT 59715

Re: Claim for a categorical exclusion for investigational use of ERYMICIN 200 (erythromycin) Injection in salmonids reared in freshwater

Dear Dr. Erdahl:

Your May 5, 2016, claim of categorical exclusion (CE), meets the criteria for CE under 21 CFR 25.33(e) for the investigational use of ERYMICIN 200 (erythromycin) Injection. The drug is proposed for investigational use in salmonids reared in freshwater for control of mortality caused by bacterial kidney disease (BKD), and control (prevention) of the vertical transmission from BKD positive female salmonid broodstock to eggs/progeny. The proposed dose is 10-25 mg erythromycin per kg/body weight (per injection). There will be 1-3 injections with a minimum interval of 21 days between injections. The maximum dosage will not exceed 75 mg/kg body weight over the three injections. Your submission also adequately states that to your knowledge no extraordinary circumstances exist that may significantly affect the quality of the human environment (21 CFR 25.21). We agree that the proposed uses of this drug as described above fall within the claimed CE and we are not aware of any extraordinary circumstances. Therefore, neither an environmental assessment (EA) nor an environmental impact statement (EIS) is required.

For all investigational sites covered under this INAD, you are responsible for complying with the Federal Clean Water Act as implemented under the National Pollutant Discharge Elimination System (NPDES), as well as any applicable ground-water pollution requirements. Prior to the use of ERYMICIN 200 Injection at any facility used in the investigations under this INAD, the offices responsible for issuing NPDES permits, and other similar effluent discharge permits, must be contacted to be certain they have no objection to the use and release of the investigational drug. You must also comply with all drug use reporting requirements specified in 40 CFR 451.3(a) for concentrated aquatic animal production facilities. In addition, this CE from the preparation of an EA and an EIS does not relieve you of the responsibility for determining and meeting all other Federal, State, and local environmental and occupational laws and regulations that apply to the manufacturing, use, and disposal of investigational drugs.

In addition, please be aware of the following conditions associated with your CE:

- You must request a new CE for protocol changes affecting the drug dose or concentration, treatment duration, frequency of use, or indications of use (including

the addition of new species at a facility) that may increase environmental exposure at individual use sites.

- You must request a new CE if you intend to treat salmonids reared in saltwater.
- You must request a new CE if new information becomes available indicating that extraordinary circumstances may exist as described in 21 CFR 25.21 due to use of the drug.

This CE only addresses the investigational use of your product. Before submitting your administrative new animal drug application (NADA), preparation of an EA for the NADA is required.

For all CE claims under 21 CFR 25.33, you should include relevant drug information to allow CVM to properly evaluate extraordinary circumstances (21 CFR 25.21), and to ensure that CVM can properly document the CE. The following should be included, if known: chemical name, established name, proprietary name, Chemical Abstracts Service registration number, chemical structure, the species, indication(s), dose, duration, frequency, route of administration, and how it will be dispensed (e.g., prescription, over-the-counter). Indicate whether the product is a nanomaterial and/or will be produced by recombinant DNA technology (e.g., by genetically engineered microorganisms). If any of the above information is not known at the time that the CE is submitted, this should be indicated in the submission.

If you submit correspondence relating to this letter, you should reference the date and the principal submission identifier found at the top of this letter. If you have any questions or comments, please contact Dr. Wesley Hunter, Toxicologist, Environmental Safety Team, at 240-402-0835. You may also contact Dr. Holly Zahner, Leader, Environmental Safety Team, at 240-402-0834.

Sincerely,

{see appended electronic signature page}
Veronica N. Taylor, Ph.D.
Director, Division of Scientific Support
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

Electronic Signature Addendum for Submission ID

I-012781-X-0001-CE

Signing Authority (Role)	Letter Date
Veronica Taylor (Division Director)	8/11/2016

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